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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,323	01/25/2002	Harry R. Davis	CV01489K	1525

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
HUI SAN MING R	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
04/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/057,323	DAVIS ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32 and 102-126* is/are pending in the application.

4a) Of the above claim(s) *105,109 and 113-125* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32,102-104,106-108,110-112 and 126* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/9/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed January 8, 2008 has been entered.

Claims 32 and 102-126 are pending in the instant application. Claims 105, 109, and 113-125 have been withdrawn as being directed to non-elected species.

Claims 32, 102-104, 106-108, 110-112, and 126 are examined insofar as they read on the elected specie.

Applicant's arguments filed January 8, 2008 with regard to Ambrosioni et al. have been considered, and a new ground of rejection is set forth citing a new reference to clarify the rejection set froth in the previous office action mailed October 22, 2007.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32, 102-104, 106-108, 110-112, and 126 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 17-20 of copending Application No. 11/897,227 ('227) in view of EP 0 457 514 ('514). '227 teaches a combination of the herein claimed sterol absorption inhibitors such as ezetimibe, and the PPAR activators such as fenofibrate. '227 does not expressly teach captopril with the combination of the herein claimed sterol absorption inhibitors such as ezetimibe, and the PPAR activators such as fenofibrate. However, '514 teaches captopril as useful in combination with cholesterol lowering agents and is useful in lowering serum choleasterol and slow the progress of atherosclerosis. Since ezetimibe and fenofibrate are well-known cholesterol lowering agents (see Rosenblum et al. - US 5,846,966 and The Medical Letter on Drugs and Therapeutics, 1998, 40;1030:68-69, both references are of record), it would be obvious at the time the invention was made to incorporate captopril with ezetimibe and fenofibrate together in a single composition useful for reducing cholesterol and the risk of atherosclerosis. One of ordinary skill in the art would have been motivated to incorporate both ezetimibe, fenofibrate, and captopril together in a single composition. The prior art teaches that ezetimibe, fenofibrate, and captopril as useful in reducing cholesterol and reduce the risk of atherosclerosis individually. Therefore, combining two or more agents, which are known to be useful to reduce cholesterol and reduce the risk of atherosclerosis individually, into a single composition useful for the very same purpose is *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069).

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32, 102-104, 106-108, 110-112, and 126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenblum et al. (US Patent 5,846,966), Medical

Letter (The Medical Letter on Drugs and Therapeutics, 1998, 40;1030:68-69), references of record, and EP 0 457 514 ('514).

Rosenblum et al. also teaches the elected compound herein, ezetimibe, useful for reducing cholesterol and the risk of artherosclerosis (See the abstract, also col. 32, Example 6, Compound 6A, and col. 40, line 52 particularly).

Medical Letter teaches fenofibrate as useful in reducing serum cholesterol level (See page 68 – 69).

'514 teaches captopril significantly reduce serum cholesterol in hypercholesterolemic patients and being beneficial as anti-atherosclerotic agents to slow or regress the progress of atherosclerosis (See page 2, lines 17-20, 30-40 for example). '514 also teaches the combination of captopril with an additional cholesterol lowering agent such as HMG-CoA reductase inhibitors (See the abstract and claims 1-3 for example).

The references do not expressly teach a composition containing fenofibrate and ezetimibe, and captopril together.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate ezetimibe, fenofibrate, and captopril together in a single composition.

One of ordinary skill in the art would have been motivated to incorporate both ezetimibe, fenofibrate, and captopril together in a single composition. The prior art teaches that ezetimibe, fenofibrate, and captopril as useful in reducing cholesterol and reduce the risk of atherosclerosis individually. Therefore, combining two or more

agents, which are known to be useful to reduce cholesterol and reduce the risk of atherosclerosis individually, into a single composition useful for the very same purpose is *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069). Furthermore, the examiner notes that captopril is known to be useful in combination with cholesterol lowering agents as disclosed in '514. Therefore, possessing the teachings of the cited prior art, one of ordinary skill in the art would have been motivated to incorporate the herein claimed actives together in a single composition for reducing cholesterol and the risk of atherosclerosis.

Response to Arguments

Applicant's arguments filed January 8, 2008 averring captopril being taught to increase serum cholesterol have been fully considered but they are not persuasive. Newly cited '514 teaches captopril as useful in reducing cholesterol in human while Ambrosioni teaches captopril increases cholesterol in rabbits. Therefore, '514 would be more relevant to the instant invention. In anyway, captopril is known to be useful in combination with cholesterol lowering agents for slowing the atherosclerosis progress and formation. Therefore, additional motivation is provided in '514 to incorporate the herein claimed actives such as the cholesterol reducing agents (ezetimibe and fenofibrate) in combination with captopril for reducing serum cholesterol as well as the risk of atherosclerosis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617

/San-ming Hui/
Primary Examiner, Art Unit 1617